

Remarks

This Amendment is in response to the Final Office Action dated **October 18, 2007**.

Rejections

35 U.S.C. 102(b)

Crocker et al.

Claims 27-29, 32-37 and 65-68 have been rejected under 35 U.S.C. §102(b) as being anticipated by Crocker et al. (6,120,523). It is asserted in the Final Office Action that “[r]egarding claims 27-29, 32-37 and 65-68, Crocker et al. discloses a medical balloon (18)... having a central body wall portion (30) between each end spaced apart from the balloon ends and connected thereto by means of tapering proximal and distal wall (38, 42) portions, respectively, wherein the balloon further comprises a lumen (32) extending longitudinally therethrough, said lumen passing through the proximal and distal wall portions of the balloon (Figures 1-4).”

Applicants disagree.

Applicants have made an amendment to claim 27 to clarify that the lumen is extending through the *tapering* proximal and distal wall portions. Antecedent basis for this is found in line 5 of claim 27 as originally filed. Thus, this amendment is only for purposes of clarification and is not a substantive amendment.

Applicants submit that there is no way in which the Crocker et al. balloon can be understood as having a lumen extending through the tapering wall portions. Applicants have reproduced the Crocker et al. balloon (Fig. 2) below to illustrate the tapering wall portions on the

Crocker et al. balloon. It is readily apparent from Fig. 2 that there is no lumen similar to that of lumen 85 of Applicants' balloon (FIG. 9 of the present specification reproduced below for illustrative purposes) extending through the tapering wall portions of the Crocker et al. balloon. Rather, the lumen 32 of the Crocker et al. balloon extends where a coaxial shaft connects the proximal end to the same or different shaft at the distal end of the balloon as recited in claim 1 and would be in a position similar to that of lumen 22 of Applicants balloon. Applicants have added reference numeral 22 and descriptions to the Crocker et al. balloon for illustration.

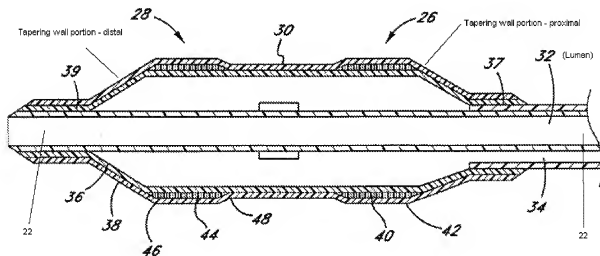
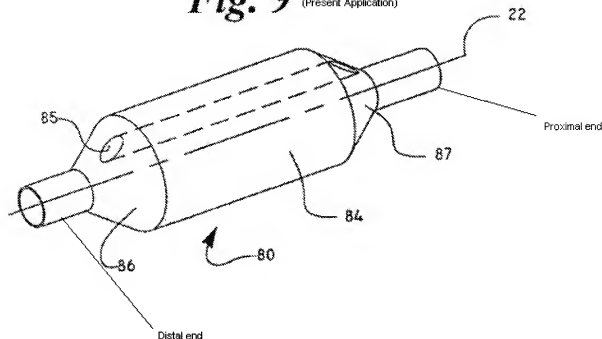


FIG. 2 (Crocker et al.)

Fig. 9 (Present Application)

It is readily apparent from FIG. 2 of Crocker et al. and compared to FIG. 9 of Applicants' specification that Crocker et al. fail to disclose a lumen 85 as recited in Applicants' independent claim that extends through the *tapering* proximal and distal wall portions.

Therefore, claim 27 is not disclosed by Crocker et al. because Crocker et al. do not disclose all of the elements of Applicants' independent claim 27 as required by 35 U.S.C. §102(b). "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987), *cert. denied*, 484 U.S. 827 (1987).

Claims 28 and 29 depend from claim 27 and are not anticipated by Crocker et al. for at least the reasons that claim 27 is not anticipated by Crocker et al.

Independent claim 32 is directed to an embodiment of an article comprising a

multi-layer polymeric material film comprising at least first and second layers said first and second layers being in adherent contact with each other over a coextensive area along respective outer and inner surfaces, *each of said first and second layers having an at-rest configuration defining an at-rest area on said respective outer and inner surfaces corresponding to said coextensive area, the at-rest area of said first layer outer surface being smaller than the at-rest area of said second layer inner surface.*

The feature of having an at rest first layer outer surface that is smaller than the second layer inner surface, results in a balloon having a surface layer that is under stress causing it to collapse to a rest position. These first layer outer surface regions are stretched from their rest configuration over the balloon, thus resulting in a first layer outer surface that is stressed. See the description for FIGS. 11A-11C, for example on page 17, lines 32-33 and page 18, lines 1-11. This stressed first layer outer surface facilitates collapse of the balloon after expansion and use.

There is simply nothing in Crocker et al. anywhere disclosing an article having, among other features, a first layer outer surface having a smaller at-rest surface area than a second layer inner surface resulting in a stressed area causing the article to collapse to a rest position.

It is asserted in the Final Office Action, in response to Applicants' arguments that:

Additionally, the Crocker et al. reference discloses "...the at-rest surface are of the first layer outer surface being smaller than the at-rest surface area of the second layer inner surface..." with the bands being elastic in nature, Applicant's Representative asserts that the bands of Crocker et al. (40, 44) can be made of polyester, which is a known elastic material, such as with textiles and many other plastics. The cited passage (col. 5, ln 36-40) lists alternate substantially nondistensible materials that are capable of some elastic expansion and contraction. Additionally, the polymer surfaces of Crocker et al. have different at-rest surface areas drawn the incorporation of the bands within the balloon assembly and impart the different stresses which are shown during inflation (Figures 2-3) in which the different regions are changed in size (near 30) and (40, 44) when compared to the different Figures (2-3).

Final Office Action, pages 4-5.

This is simply not what Crocker et al. discloses.

The Crocker et al. bands 40, 44 are clearly disclosed as being formed on nondistensible materials, not elastic materials. Polyester is disclosed by Crocker et al. as being a nondistensible material, not an elastic material. These non-distensible materials are for the purpose of limiting expansion. See the paragraph at col. 5, lines 33-43 of Crocker et al.

Furthermore, there is no disclosure by Crocker et al. to stretch these bands over the balloon so that the outer surface area of the coextensive area of the expansion limiting bands 40, 44 is smaller than the underlying balloon inner surface area. Rather, it is simply the nondistensible (inelastic) nature that provides expansion limiting characteristics. Crocker et al. is silent as to these bands providing stress so as to collapse the article as disclosed in Applicants' specification. The only stretching discussed by Crocker et al. reference is axial (lengthwise) stretching of the balloon to provide a balloon with portions that have a thinner wall. See col. 7, lines 11-28 and particularly, see col. 8, lines 62-67. This type of stretching for wall thinning purposes is known to those of ordinary skill in the art. The disclosure of Crocker et al. is being expanded to encompass what simply is not there.

This axial or lengthwise stretching is not equivalent to stretching so as to provide an outer surface having a smaller surface area than an inner surface for purposes of collapsing an article as recited in independent claim 32.

Claim 32 is therefore not anticipated by Crocker et al.

Claims 33-37 depend from claim 32 and are not anticipated by Crocker et al. for at least the reasons that claim 32 is not anticipated by Crocker et al.

Claim 65 is directed to an embodiment of a balloon wherein the balloon body has

proximal and distal ends, and the balloon including circumferential elastic bands at the proximal end or distal end of the balloon body, the elastic bands in their rest configuration have a smaller diameter than the balloon body in its at rest configuration.

This claim is patentable for reasons similar to that discussed above with respect to claim 32. The elastic bands having a smaller diameter than the under-lying balloon layer, causes this area to be stressed so as to collapse the balloon. See col. 7, lines 11-28 and particularly see col. 8, lines 62-67. These bands are stretched over the balloon in order to provide the bands with a smaller diameter than the underlying balloon layer.

Crocker et al. simply fail to disclose such a feature.

The bands 40, 44 disclosed by Crocker et al. are formed from nondistensible materials as discussed above. These bands are disclosed by Crocker et al. as being expansion limiting, but Crocker et al. is silent as to these bands having a smaller diameter than the underlying balloon, and as such, providing an area of stress in order to facilitate collapse of the balloon after expansion.

Again, the only stretching provided by the Crocker et al. reference is axial (lengthwise) stretching of the balloon to provide a balloon with portions that have a thinner wall. See col. 7, lines 11-28 and particularly, see col. 8, lines 62-67. This type of stretching for wall thinning purposes is known to those of ordinary skill in the art. The disclosure of Crocker et al. is being expanded to encompass what simply is not there.

Thus, claim 65 is also not anticipated by Crocker et al.

Claims 66-68 depend from claim 65 and are not anticipated by Crocker et al. for at least the reasons that claim 65 is not anticipated by Crocker et al.

Applicants respectfully request withdrawal of the rejection of claims 27-29, 32-37

and 65-68 under 35 U.S.C. §102(b) as being anticipated by Crocker et al. (6,120,523).

Hamlin

Claims 27-29, 32-37 and 38 have been rejected under 35 U.S.C. §102(b) as being anticipated by Hamlin (6,132,824). It is asserted in the Final Office Action that:

Regarding claims 27-29, 32-35, and 38 Hamlin discloses a medical balloon (40, 58)...connecting to a coaxial shaft (50) at a proximal end thereof and connecting to the same or a different coaxial shaft (50) at a proximal end thereof and connecting to the same or a different coaxial shaft at the distal end thereof (62), and having a central body wall portion (near 68) between each end spaced apart from the balloon ends and connected thereto by means of tapering proximal and distal wall (Figures 5-6) portions, respectively, wherein the balloon further comprises a lumen (52) extending longitudinally therethrough, said lumen passing through the proximal and distal wall portions of the balloon (Figures 5-6).

Page 3 of the Final Office Action.

Applicant disagrees.

As discussed above, claim 27 was amended to more clearly recite that the lumen extends longitudinally through the tapering proximal and distal wall portions. The balloon of Hamlin (Figures 5-6), like that of Crocker et al., fails to include a lumen extending longitudinally through the tapering proximal and distal wall portions. Lumen (52) of the Hamlin balloon does not extend through the tapering proximal and distal wall portions of the balloon, and is in a position similar to that of lumen (22) disclosed in Applicants' specification.

Therefore, the balloon disclosed by Hamlin, fails to anticipate the balloon recited in claim 27. Claims 28 and 29 depend from claim 27 and are not anticipated by Hamlin for at least the reasons that claim 27 is not anticipated by Hamlin.

It is asserted in the Final Office Action, with respect to claim 32, that "Hamlin discloses a polymeric balloon....that is comprised of a multi-layer polymeric film (64, 66, 68)

wherein first (64, 66) and second layers are in adherent contact over a coplanar coextensive region and at rest and open configuration resulting in a change of surface area (Figures 5-6).

Applicants traverse the rejection with respect to claim 32.

Claim 32 has been discussed above and is directed to an embodiment wherein an article includes first and second layers wherein first and second layers being in adherent contact with each other over a coextensive area along respective outer and inner surfaces, *each of said first and second layers having an at-rest configuration defining an at-rest area on said respective outer and inner surfaces corresponding to said coextensive area, the at-rest area of said first layer outer surface being smaller than the at-rest area of said second layer inner surface.*

Thus, a balloon that simply has an at-rest and open configuration resulting in a change of surface area, does not anticipate claim 32 which recites, among other features, a first layer outer surface having a smaller surface area than the second layer inner surface, resulting in a stressed region that can lead to balloon collapse. Again, see page 17, lines 32-33 and page 18, lines 1-11.

Because all of the elements of claim 32 are not disclosed, claim 32 is not anticipated. See *Verdegaal Bros. v. Union Oil Co. of California*, 2 USPQ2d at 1053.

Claims 33-37 and 38 depend from claim 32 and are not anticipated by Hamlin for at least the reasons that claim 32 is not anticipated by Hamlin.

Applicants respectfully request withdrawal of the rejection of claims 27-29, 32-37 and 38 under 35 U.S.C. §102(b) as being anticipated by Hamlin (6,132,824).

Boussignac et al.

Claims 63-64 have been rejected under 35 U.S.C. §102(b) as being anticipated by

Boussignac et al. (5,000,734). It is asserted in the Final Office Action that “[r]egarding claims 63-64, Boussignac et al. disclose a medical balloon...having a central body wall (near 1) portion connected with tapering wall portions (near 5a, 5b), wherein the balloon comprises a lumen (11) extending therethrough, the lumen spaced apart from the coaxial shaft (Figure 3).”

Applicants have amended claim 63.

Claim 63 as amended and is directed to an embodiment wherein the balloon is formed from a radiation cured polymerizable composition.

Boussignac et al. fail to disclose the use of a radiation cured polymerizable composition for forming the bag element disclosed therein.

Thus, Boussignac et al. fail to disclose all of the elements of claim 63 as amended as required by 35 U.S.C. §102(b). See *Verdegaal Bros. v. Union Oil Co. of California* at 1053.

Claim 64 depends from claim 63 and is not anticipated by Boussignac et al. for at least the reasons that claim 63 is not anticipated by Boussignac et al.

Applicants respectfully request withdrawal of the rejection of claims 63-64 under 35 U.S.C. §102(b) as being anticipated by Boussignac et al. (5,000,734).

White, Jr.

Claim 65 has been rejected under 35 U.S.C. §102(b) as being anticipated by White, Jr. (4,327,734). It is asserted in the Final Office Action that “[r]egarding claim 65, White, Jr. discloses a balloon (20) comprising a balloon body (38) having a proximal and distal end, and the balloon comprising circumferential elastic bands (46) at the proximal end or distal end of the balloon body, the elastic bands (46) in their rest configuration have a smaller diameter than the balloon body in its rest configuration (Figure 1) versus the inflated configuration (Figures 2-3)

(Figures 1-3).” Final Office Action, pages 4-5.

Applicants traverse the rejection.

Claim 65 is directed to an embodiment wherein the balloon body has proximal and distal ends, and the balloon including circumferential elastic bands at the proximal end or distal end of the balloon body, the elastic bands in their rest configuration *have a smaller diameter* than the balloon body in its at rest configuration.

White, Jr. discloses that an elastic band 46 that assists in retaining a pin in the self-sealing plug:

Surrounding the portion of the balloon where the plug 34 is located on the exterior surface thereof is an elastic band 46 of plastic or rubber material which assists in retaining the pin in the self-sealing plug and is utilized to assist with the self-sealing plug in sealing the open end of the balloon when the cannula and pin combination is removed therefrom during detachment. A secondary small chamber 48 between the end of the cannula 22 and the self-sealing plug 34 communicates with side opening 32 and provides the area for additional fluid utilized to expand end portion 36 of the balloon and facilitate withdrawal of the cannula and pin therefrom during detachment.

Col. 3, lines 40-52.

White, Jr. is silent as to the elastic band 46 having a smaller diameter than the underlying balloon so that the area is stressed and will facilitate collapse of the balloon and is silent as to stretching the band over the balloon so as to accomplish such. See page 17, lines 32-33 and page 18, lines 1-11 of the present specification.

Thus, not all of the elements of claim 65 are disclosed by White, Jr. as required by 35 U.S.C. §102(b). *Id.* at 1053.

Applicant respectfully requests withdrawal of the rejection of claim 65 under 35 U.S.C. §102(b) as being anticipated by White, Jr. (4,327,734).

Anderson

Claims 63-64 have been rejected under 35 U.S.C. §102(b) as being anticipated by Anderson (6,007,517). It is asserted in the Final Office Action that “[r]egarding claims 63-64, Anderson discloses a medical balloon (3) catheter (1) (Figures 1C, 2A, 3A, 10A and 11A)...formed of polymer material, the balloon connecting to a coaxial shaft (2) at the proximal end thereof and connecting to the same or a different coaxial shaft at the distal end thereof, and having a central body wall (near 7) portion connected with tapering wall portions (near 5 and 6), wherein the balloon comprises a lumen (7) extending therethrough, the lumen spaced apart from the coaxial shaft (Figures 3A and 11A).” Final Office Action, page 5.

As discussed above, claim 63 has been amended and is now directed to an embodiment wherein the balloon is formed of a radiation cured polymerizable composition.

Anderson fails to disclose the use of a radiation cured polymerizable composition for forming the balloon dilatation catheter disclosed therein.

Thus, Anderson fails to disclose all of the elements of claim 63 as amended as required by 35 U.S.C. §102(b). *Id.* at 1053.

Claim 64 depends from claim 63 and is not anticipated by Anderson for at least the reasons that claim 63 is not anticipated by Anderson.

Applicants respectfully request withdrawal of the rejection of claims 63-64 under 35 U.S.C. §102(b) as being anticipated by Anderson (6,007,517).

35 U.S.C. §103(a)

Claims 30-31 have been rejected under 35 U.S.C §103(a) as being unpatentable

over Crocker et al. It is asserted in the Final Office Action that “Crocker et al. meets the claim limitations as described above except for the specific embodiment being used in with a stent or with a rapid exchange catheter.... At the time of the invention, it would have been obvious to use the medical balloon as disclosed by the various embodiments and the disclosure of Crocker et al. in order to achieve a versatile controllable balloon element.”

Claims 30-31 depend from claim 27.

Claim 27 is not obvious over Crocker et al. because Crocker et al. fail to disclose or to suggest a lumen 85 as recited in claim 27 that extends through the *tapering* proximal and distal wall portions. This was discussed at length above.

Claims 30-31 are not obvious over Crocker et al. for at least the reasons that claim 27 is not obvious over Crocker et al.

Applicants respectfully request withdrawal of the rejection of claims 30-31 under 35 U.S.C §103(a) as being unpatentable over Crocker et al.

CONCLUSION

Claims 27, 28, 30-38 and 63-68 are pending in the application. Applicants have addressed all of the issues presented in the Final Office Action. Based on the foregoing, Applicants respectfully request reconsideration and an early allowance of the claims as presented. Should any issues remain, the attorney of record may be reached at (952)563-3011 to expedite prosecution of this application.

Respectfully submitted,

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